



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2012, from 8:30 a.m. to 4 p.m.

Location: DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301-589-5200.

Contact Person: Walter Ellenberg, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD. 20993, 301-796-0885, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at

<http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 11, 2012, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107-109) and the Pediatric Research Equity Act (Public Law 108-155), for Kapvay (clonidine hydrochloride), Vyvanse (lisdexamfetamine dimesylate), Ofirmev (acetaminophen), ella (ulipristal acetate), Beyaz (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Lo Loestrin Fe (norethindrone acetate and ethinyl estradiol ethinyl estradiol and ferrous fumarate), Aridol (mannitol inhalation powder), Augmentin XR (amoxicillin/clavulanate potassium), Afinitor (everolimus), Moxeza (moxifloxacin hydrochloride), and Lastacraft (alcaftadine).

As mandated by the Food and Drug Administration Amendments Act, Title III, Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85), the committee will discuss the safety of and the ongoing propriety of the humanitarian device exemption for the Melody Transcatheter Pulmonary Valve and Ensemble Delivery System and the Elana Surgical Kit.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at

<http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 4, 2012. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on September 11, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 24, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 27, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg (walter.ellenberg@fda.hhs.gov) or 301-796-0885 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 24, 2012.
Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

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